



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

msllsh

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

January 24, 2001

Our Reference: 2923402

Takashi Shimosaka, President
Kibun Foods (U.S.A.), Inc.
1111 Third Avenue, # 1860
Seattle, Washington 98101

WARNING LETTER

Dear Mr. Shimosaka:

On July 5, 7, and 12, 2000, we inspected your seafood firm, Kibun Foods (U.S.A.), Inc., located at 834 Pohukaina Stree, Honolulu, Hawaii 96813. We conducted this inspection to determine your compliance with FDA's Seafood HACCP regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP and GMP deviations. These deviations cause your refrigerated vacuum packed and/or modified atmosphere packed fish cakes to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions, whereby they may be rendered injurious to health. We listed the deficiencies on a Form FDA 483 and discussed them with Mr. Noriaki Suzuki, Vice President, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your reference. Your serious HACCP and GMP deviations are as follows:

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 123.6(c)(3).

- (a) However, your firm's HACCP plans for **Pasteurized Deep Fried Fish Cakes (Kushiten)**, **Steamed Fish Cakes (Kamaboko)**, and **Broiled Fish Cakes (Chikuwa)** do not list a critical limit at the Formulation/Mixing critical control point to control *Clostridium botulinum*. If you have not established (by a scientific study) that your process will consistently attain a water activity of [REDACTED] or lower, you must list an appropriate water activity level as a critical limit in your HACCP and provide adequate monitoring procedures and frequencies for each lot of product.
- (b) However, your firm's HACCP plan for **Pasteurized Deep Fried Fish Cakes (Kushiten)** does not list a critical limit at your Vacuum Packing critical control point to control the Introduction of Pathogens after Pasteurization. You must have monitoring procedures for conducting detailed examinations of your pouch integrity. Chapter 18 of the Fish & Fishery Products Hazards and Controls Guide can help provide the necessary guidelines.
- (c) However, your HACCP plan for **Pasteurized Deep Fried Fish Cakes (Kushiten)** does not list a critical limit at the Vacuum Packing critical control point to control Pathogen Growth after Pasteurization. You must monitor the chlorination of the water used to check the integrity of the seals of your sealed packs.
- (d) However, your firm's HACCP plan for **Broiled Fish Cakes (Chikuwa)** lists a critical limit at the Gas Broil critical control point that is not adequate to control the hazard of Pathogen Survival through Cooking. Your plan lists the critical limits of [REDACTED] degrees Celsius (broiler temperature) and [REDACTED] minutes cook time. Your product must reach an internal temperature of [REDACTED] degrees Celsius for [REDACTED] minutes to control the hazard of *Clostridium botulinum*.
- (e) However, your firm's HACCP plans for **Broiled Fish Cakes (Chikuwa)**, **Steamed Fish Cakes (Kamaboko)**, and **Pasteurized Deep Fried Fish Cakes (Kushiten)** list time and temperature critical limits at the Air Cooling critical control point that are not adequate to control the hazard of Pathogen Growth. In addition to the time and temperature critical limits you have already established, your product must receive additional cooling and its temperature should reach [REDACTED] degrees Celsius within another [REDACTED] hours.

2. You must have a HACCP plan that lists the critical control points to comply with 21 CFR 123.6(c)(2).

(a) However, your firm's HACCP plan for **Pasteurized Deep Fried Fish Cakes (Kushiten)** does not list the critical control point of Cooling after Pasteurization for controlling the food safety hazard of *Clostridium botulinum*.

(b) However, your firm's HACCP plans for **Steamed Fish Cakes (Kamaboko)** and **Broiled Fish Cakes (Chikuwa)** do not list the critical control point of refrigerated storage for controlling the hazard of histamine formation. If you store the fresh marlin you receive either iced or refrigerated, you must monitor your storage conditions to assure that the fish remains adequately cooled.

3. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b).

(a) However, your firm did not follow the monitoring procedure of monitoring temperature gauges at the Pasteurization () critical control point to control Pathogen Survival Through Pasteurization listed in your HACCP plan for **Deep Fried Fish Cakes (Kushiten)**. No actual temperature gauge readings were recorded in your records. Your monitoring record for 6/30/00 indicates only the temperature setting for the steamer and provides another place to record the core temperature from a sample.

(b) However, your firm did not follow the monitoring procedure for checking the metal detector at the Metal Detection critical control point listed in your HACCP plans for **Deep Fried Fish Cakes (Kushiten)**, **Steamed Fish Cakes (Kamaboko)**, and **Broiled Fish Cakes (Chikuwa)**. Your HACCP plans list your critical limit as mm for ferrous metal and m for non-ferrous metal. Your monitoring records indicate that your metal detector sensitivity is set for mm for ferrous metal and for non-ferrous metal.

4. However, your firm did not follow the monitoring procedure of monitoring the temperature of your product at the Air Cooling critical control point to control the hazard of Pathogen Growth & Toxin Formation listed in your HACCP plans for **Steamed Fish Cakes (Kamaboko)**, and **Broiled Fish Cakes (Chikuwa)**. Your monitoring procedure lists that you will monitor time and temperature by "monitoring cooling time and length of cooling cycle via baby dial thermometers and time

recorder.” Your monitoring record (Packing Room Metal Detector Check List) does not indicate, or have a place to record, the temperature of your product at the end of cooling.

5. You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the following areas of sanitation with sufficient frequency to ensure control:

- Condition and cleanliness of food contact surfaces – Inadequately cleaned equipment in use in processing area.
- Maintenance of handwashing and sanitizing facilities – No sanitizing solutions or hand dips are available in the processing/packing rooms.
- Proper labeling and storage of toxic compounds – Unlabeled food-grade machine oil present in the processing area.
- Protection of food and food contact surfaces from contamination – Food observed held in areas where splash from floors likely. Insanitary fans used to cool exposed cooked product.
- Prevention of cross-contamination – Raw and Cooked products inadequately separated.

6. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm maintained sanitation control records that were not adequate.

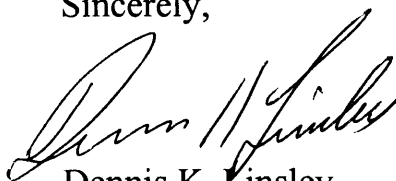
We may take further regulatory action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You may wish to include in your response documentation such as time/temperature monitoring records, sanitation records, revised HACCP plans, etc. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley", written in a cursive style.

Dennis K. Linsley
Director
San Francisco District

Enclosure

cc: VIA FEDERAL EXPRESS
Noriaki Suzuki, Vice President
Kibun Foods (U.S.A.), Inc.
506 Ahui Street
Honolulu, Hawaii 96813
Phone: (808) 591-2091